IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. WEST-WARD PHARMACEUTICAL CORPORATION, HIKMA AMERICAS INC., and HIKMA PHARMACEUTICALS PLC, Defendants.	Civil Action No. _____

COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") files this Complaint for declaratory judgment of patent infringement against Defendants West-Ward Pharmaceutical Corporation, Hikma Americas Inc., and Hikma Pharmaceuticals PLC (collectively, "Hikma") and, in support thereof, alleges as follows.

NATURE OF THE ACTION

1. This is an action for declaratory judgment of patent infringement under the Declaratory Judgment Act, Title 28 United Code §§ 2201, 2202, and the patent laws of the United States, Title 35, United States Code based on Hikma's plan to market and sell in the United States its product MITIGARE™ (colchicine) 0.6 mg capsules.

THE PARTIES

2. Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. Takeda holds all right, title and interest in each patent asserted in this action.

3. On information and belief, West-Ward Pharmaceutical Corporation ("West-Ward") is a corporation organized and existing under the laws of the State of Delaware with a

principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724. Upon information and belief, West-Ward acts as a domestic marketer, manufacturer, and distributor of drug products for sale and use throughout the United States for entities affiliated with Hikma Pharmaceuticals PLC. West-Ward's website states the following: "West-Ward Pharmaceuticals is one of the top 20 generic prescription medication providers in the US, providing pharmaceuticals to a growing number of chain stores, wholesalers, distributers, health systems and government agencies. We are the US agent and subsidiary of Hikma PLC." West-Ward's website also indicates that it has a sales representative for the State of Delaware. On information and belief, West-Ward has active pharmacy wholesaler and controlled substance distributer and manufacturer licenses in Delaware. On information and belief, West-Ward is a wholly-owned subsidiary of Eurohealth (U.S.A.) Inc., and its parent, Hikma Pharmaceuticals PLC.

4. On information and belief, Hikma Americas Inc. ("Hikma Americas") is a company incorporated in the State of Tennessee with a place of business at 5865 Ridgeway Center Parkway, Suite 300 Memphis, TN, 38120. On information and belief, Hikma Americas is a wholly-owned subsidiary of Hikma Pharmaceuticals PLC. On information and belief, Hikma Americas will sell and offer for sale, the MITIGARE™ product in the United States and including in this District. Hikma Americas website (www.hikma-americas.com) lists MITIGARE™ as a product available for purchase. On information and belief, Hikma Americas is also identified on the MITIGARE™ product label as the entity that West-Ward manufactures MITIGARE™ for distribution.

5. On information and belief, Hikma Pharmaceuticals PLC ("Hikma Pharmaceuticals") is a company incorporated in the United Kingdom with a place of business at 13 Hanover Square, London, W1S 1HL, United Kingdom. Hikma Pharmaceuticals is a

worldwide pharmaceutical company in the business of developing and manufacturing branded and generic drugs. According to Hikma Pharmaceuticals' website, Hikma Pharmaceuticals' generics business in the United States "operates as West-Ward Pharmaceuticals, a domestic marketer and manufacturer of generic pharmaceutical products."

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 because this action involves an actual controversy concerning Hikma's imminent infringement of Takeda's patents.

7. This Court has personal jurisdiction over West-Ward because, among other reasons, it is a Delaware corporation, it has extensive contacts with the State of Delaware, and West-Ward regularly does business in this district.

8. West-Ward is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation under the laws of the State of Delaware, and its conduct of business in this District. On information and belief, West-Ward develops, formulates, manufactures, markets, and sells drug products throughout the United States, including Delaware, and Delaware is a likely destination of West-Ward's products. On information and belief, West-Ward has purposely availed itself of the rights and benefits of the laws of the State of Delaware, and has engaged in substantial and continuous contacts with the State of Delaware.

9. Hikma Americas is subject to personal jurisdiction in this District because, *inter alia*, alone and/or together with West-Ward (which is incorporated under the laws of the State of Delaware), Hikma Americas has, on information and belief, purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Hikma Americas, together with West-Ward and Hikma

Pharmaceuticals, regularly and continuously transacts business within the State of Delaware, including, but not limited to, receiving pharmaceuticals from West-Ward for distribution within the United States generally, and within this District. Additionally, the Hikma Americas website specifically instructs visitors to the website to place an order for MITIGARE™. On information and belief, Hikma Americas will sell MITIGARE™ in the United States including in this District. On information and belief there is no restriction on the sale of MITIGARE™ to residents of the State of Delaware and residents in this District are freely able to access the Hikma Americas website to secure purchase of MITIGARE™.

10. Hikma Pharmaceuticals is subject to personal jurisdiction in this District because, *inter alia*, alone and/or together with its agent West-Ward (which is incorporated under the laws of the State of Delaware), Hikma Pharmaceuticals has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Hikma Pharmaceuticals, together with West-Ward, regularly and continuously transacts business within the State of Delaware, including, but not limited to, shipping pharmaceuticals to West-Ward from locations outside the United States for distribution by West-Ward within the United States generally, and within this District specifically.

11. In the alternative, this Court has personal jurisdiction over Hikma Pharmaceuticals under Fed. R. Civ. P. 4(k)(2) because this action arises under federal law and, upon information and belief, Hikma Pharmaceuticals is not subject to the general jurisdiction of the courts of any state and the exercise of personal jurisdiction over Hikma Pharmaceuticals is consistent with the Constitution and the laws of the United States.

12. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

STATEMENT OF FACTS RELEVANT TO ALL COUNTS

13. COLCRYS® is primarily used to prevent and treat gout flares. Gout is a type of severe arthritis typically characterized by extremely painful "flares" (severe and sudden attacks of pain, redness, inflammation, and tenderness in joints) resulting from a build-up of uric acid. COLCRYS® is the only oral single-ingredient colchicine product approved by the FDA to treat and prevent gout flares.

14. The FDA approved COLCRYS® for marketing in the United States under New Drug Application ("NDA") Nos. 22-351, 22-352 and 22-353 pursuant to section 505(b) of the Federal Food Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 355(b).

15. In 2009, as a result of extensive research by Mutual Pharmaceutical Company, Inc. ("Mutual"), a former affiliate of Takeda, the FDA for the first time approved an oral single-active-ingredient colchicine product: COLCRYS®. Through its groundbreaking research, Mutual discovered important new information about colchicine, including previously unknown information concerning safety and efficacy, tolerability, dangerous side effects, and interactions with other medicines and substances.

16. Prior to COLCRYS®, there was no FDA-approved application demonstrating the safety and effectiveness of oral single-ingredient colchicine. The lack of FDA-reviewed data regarding oral single-ingredient colchicine was particularly troublesome because colchicine is potentially toxic. FDA has reported more than 160 deaths associated with oral colchicine. Accordingly, to better understand the toxicities, Mutual developed its own formulation and conducted numerous studies to support the safe and effective use of an oral single-ingredient colchicine product.

17. One of Mutual's clinical studies, the Acute Gout Flare Receiving Colchicine Evaluation ("AGREE") trial, provided important new information on the optimal dose of

colchicine for treatment of gout flares. Traditionally, oral colchicine has been dosed for the treatment of gout flares by administering an initial dose of one to two tablets followed by additional doses every one to two hours until pain is relieved or until "nausea, vomiting, or diarrhea develops." The usual dose totaled between 4 and 8 mg of colchicine, which was expected to result in toxicity-related side effects such as diarrhea or vomiting.

18. The AGREE trial completely upended the conventional wisdom. The trial was a double-blind, placebo-controlled, multicenter, dose-comparison study involving 575 trial participants that compared the effects of the "traditional" dose versus a lower dose of just 1.8 mg total. The AGREE trial proved that the lower dose regimen is just as effective as the higher traditional dose regimen but without the serious adverse events of the higher dose. Based on Mutual's trial, the FDA approved Mutual's colchicine product with the low dose regimen as safe and effective for the treatment of gout flares. The COLCRYS® low dose regimen is in the FDA approved product label attached as Exhibit A.

19. In 2012, the American College of Rheumatology ("ACR") issued guidelines for management of gout. The ACR recommends treating an acutre gout flare by using a loading dose of 1.2 mg of colchicine, followed by 0.6 mg 1 hour later, and then, 12 hours later, resuming 0.6 mg prophylactic dosing once or twice daily, unless dose adjustment is necessary. The ACR guidelines adopt Takeda's low dose regimen. The ACR recommendation remains the standard of care for the use of colchicine to treat acute gout flares. The ACR guidelines are attached as Exhibit B.

20. Mutual also conducted multiple studies regarding potential adverse drug interactions involving colchicine. Mutual researched numerous drug interactions that could result in unsafe levels of colchicine and even death. Mutual discovered, for example, that co-

administering colchicine with clarithromycin could increase colchicine blood levels by nearly 230%. Due to Mutual's work, potentially dangerous interactions have been identified and characterized and doctors and patients are now better informed. As a result of Mutual's research, appropriate dosing reductions to reduce the risk of an adverse reaction during concomitant administration with other agents, and the corresponding dose adjustment information, is included in the approved labeling for COLCRYS®.

21. Based on its studies, Mutual also discovered the correct dose adjustments for the safe use of colchicine with strong and moderate CYP3A4 inhibitors, P-gp inhibitors, and protease inhibitors. The new dosing information is important to prevent unnecessary toxicity and even death and is included in the approved labeling for COLCRYS®. For example, the dose adjustment table in the COLCRYS® labeling provides that the prophylactic dose of colchicine, when used with a strong CYP3A4 inhibitor such as clarithromycin, should be adjusted from 0.6 mg twice per day to 0.3 mg once per day, which can be accomplished by altering the frequency and amount of a 0.6 mg dose. If the original intended prophylactic dose is 0.6 mg once a day, then the dose should be adjusted to 0.3 mg once every other day, which can be accomplished by altering the frequency and amount of a 0.6 mg dose. The COLCRYS® labeling also provides dose adjustments when coadministered with ketoconazole, verapamil, and other drugs such as protease inhibitors.

TAKEDA'S COLCRYS® PATENTS

22. Takeda is the lawful owner of all right, title, and interest in and to the following United States patents, including the right to sue and to recover for infringement thereof, which contain one or more claims covering methods of use of COLCRYS®.

A. United States Patent Number 7,964,647 ("the '647 Patent"), titled "COLCHICINE COMPOSITIONS AND METHODS," a copy of which is attached hereto as

Exhibit C and incorporated herein by reference as though set forth in full, which was duly and legally issued June 21, 2011, naming Matthew Davis as the inventor.

B. United States Patent Number 7,964,648 ("the '648 Patent"), titled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit D and incorporated herein by reference as though set forth in full, which was duly and legally issued June 21, 2011, naming Matthew Davis as the inventor.

C. United States Patent Number 7,981,938 ("the '938 Patent"), titled "COLCHICINE COMPOSITIONS AND METHODS," a copy of which is attached hereto as Exhibit E and incorporated herein by reference as though set forth in full, which was duly and legally issued July 19, 2011, naming Matthew Davis as the inventor.

D. United States Patent Number 8,097,655 ("the '655 Patent"), titled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," a copy of which is attached hereto as Exhibit F and incorporated herein by reference as though set forth in full, which was duly and legally issued January 17, 2012, naming Matthew Davis as the inventor.

E. United States Patent Number 8,440,722 ("the '722 Patent"), titled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit G and incorporated herein by reference as though set forth in full, which was duly and legally issued May 14, 2013, naming Matthew Davis as the inventor.

23. All of the above-listed patents are collectively referred to herein as the "COLCRYS® Patents."

HIKMA'S ACTIONS GIVING RISE TO THIS SUIT

24. On or about October 5, 2012, Hikma Pharmaceuticals, with the assistance of West-Ward, submitted an NDA to the FDA, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for the approval to market and sell an oral single-ingredient colchicine product.

25. On September 26, 2014, the FDA approved Hikma's NDA No. 204820 for the use of MITIGARE™ (colchicine) 0.6 mg capsules for the prophylaxis of gout flares.

26. Hikma's MITIGARE™ product contains the same active ingredient, colchicine, as COLCRYS®. Hikma's MITIGARE™ also uses the same route of administration (oral) and dosage strength (0.6 mg) as COLCRYS®. A copy of the MITIGARE™ product label is attached as Exhibit H.

27. On information and belief, Hikma has made concrete plans to manufacture, advertise, promote, market, offer to sell and sell its MITIGARE™ product in the United States to compete directly with COLCRYS®.

28. Between 1972 and October 2010, Hikma manufactured, advertised, promoted, marketed and sold unapproved oral single-ingredient colchicine 0.6 mg tablets that contain the same active ingredient as MITIGARE™. On information and belief, Hikma can and will use the same manufacturing facilities, advertising and marketing resources and sales channels that Hikma previously used for its unapproved 0.6 mg colchicine tablet to manufacture, advertise, promote, market, offer for sale and sell the MITIGARE™ capsule product.

29. On information and belief, Hikma is preparing to solicit and receive orders for its MITIGARE™ capsule product.

30. On information and belief, Hikma intends that MITIGARE™ will be used by the same patients that are currently using COLCRYS® to treat and prevent gout flares.

31. COLCRYS® and MITIGARE™ both consist of 0.6 mg colchicine and the pharmacological properties of the two drug products are the same.

32. COLCRYS® is approved for both prophylaxis and treatment of acute gout flares, while MITIGARE™ is approved only for prophylaxis. Nevertheless, the same 0.6 mg of colchicine may be used for either prophylaxis or treatment of acute gout flares.

33. Because MITIGARE™ contains the same amount of colchicine as COLCRYS® and because the standard of care endorsed by the ACR to treat acute gout flares is to administer colchicine at the first sign of the flare in accordance with the low-dose regimen invented by Takeda and stated in the COLCRYS® product labeling, Hikma knows and intends that patients using its MITIGARE™ product will also use its MITIGARE™ product to treat the acute gout flare by following the low-dose regimen found on the COLCRYS® product insert. The Medication Guide for MITIGARE instructs patients to tell a healthcare provider if they have a gout flare while taking MITIGARE, but does not direct patients to stop taking the product upon experiencing a flare.

34. On information and belief, Hikma will make no effort to stop doctors or patients from using its 0.6 mg colchicine product in an infringing manner. Hikma's product labeling does not instruct doctors or patients not to use MITIGARE™ to treat acute gout flares. The only reference in Hikma's label about the treatment of acute gout flares is a statement that "[t]he safety and effectiveness of MITIGARE™ for acute treatment of gout flares during prophylaxis has not been studied." On information and belief, this statement refers only to ***Hikma*** not having done such studies. Hikma knows full well that Mutual *did* study the safety and effectiveness of

0.6 mg colchicine in treating acute gout flares, as described in the COLCRYS® product labeling. Indeed, in 2011 Hikma opposed a Citizen Petition filed by Mutual that involved Mutual's AGREE clinical trial and the low dose regimen. On information and belief, because Hikma fails to specify how to safely and effectively use colchicine to treat an acute gout flare, doctors and patients will inevitably have to consult the COLCRYS® product label or the ACR guidelines (endorsing the same low dose regimen) that describe the specific dosing regimen for treating acute gout flares using colchicine. By knowingly intending the use of Takeda's patent-protected low-dose regimen, Hikma actively induces infringement of one or more claims of the '938 and '647 patents.

35. Similarly, Hikma's product labeling instructs doctors or patients, when co-administering MITIGARE™ with certain other active agents, e.g., clarithromycin, ketoconazole, verapamil, that "the dose of MITIGARE™ should be adjusted by either reducing the daily dose or reducing the dose frequency, and the patient should be monitored for colchicine toxicity." Hikma does not specify the amount by which the daily dose of colchicine should be reduced. And Hikma is aware that Takeda's COLCRYS® product is the only oral single-ingredient colchicine product approved by the FDA for the prophylactic treatment of gout flares in patients receiving concomitant administration of clarithromycin, ketoconazole, or verapamil.

36. Hikma knows full well that Mutual studied the safety and effectiveness, as well as dose adjustment, of colchicine in the presence of CYP3A4 and P-gp inhibitors and that such information is found in the COLCRYS® product label. On information and belief, because Hikma fails to specify how to reduce the dose or dose frequency, doctors and patients will inevitably have to consult the dose regimens set forth in the COLCRYS® product labeling to safely and effectively use its MITIGARE™ product. By knowingly intending use of Takeda's

patent-protected adjusted-dosing regimens, Hikma actively induces infringement of one or more claims of the '655, '648, and '722 patents.

COUNT I

(Declaratory Infringement of the '647 Patent Under 35 U.S.C. § 271(b))

37. Paragraphs 1 to 36 are incorporated herein as set forth above.

38. There is an actual and substantial controversy between Takeda and Hikma regarding the imminent infringement of the '647 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

39. Unless enjoined by the Court, Hikma will induce infringement of the '647 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell MITIGARE™ in the United States.

40. On information and belief, Hikma will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using MITIGARE™, with knowledge of the '647 Patent and knowledge that its acts are encouraging infringement.

41. Takeda will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court.

42. Takeda does not have an adequate remedy at law.

43. Takeda requests a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of MITIGARE™ before the '647 Patent expires will induce infringement of one or more claims of the '647 Patent.

COUNT II

(Declaratory Infringement of the '648 Patent Under 35 U.S.C. § 271(b))

44. Paragraphs 1 to 43 are incorporated herein as set forth above.

45. There is an actual and substantial controversy between Takeda and Hikma regarding the imminent infringement of the '648 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

46. Unless enjoined by the Court, Hikma will induce infringement of the '648 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell MITIGARE™ in the United States.

47. On information and belief, Hikma will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using MITIGARE™, with knowledge of the '648 Patent and knowledge that its acts are encouraging infringement.

48. Takeda will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court.

49. Takeda does not have an adequate remedy at law.

50. Takeda requests a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of MITIGARE™ before the '648 Patent expires will induce infringement of one or more claims of the '648 Patent.

COUNT III

(Declaratory Infringement of the '938 Patent Under 35 U.S.C. § 271(b))

51. Paragraphs 1 to 50 are incorporated herein as set forth above.

52. There is an actual and substantial controversy between Takeda and Hikma regarding the imminent infringement of the '938 Patent, and this controversy is of sufficient

immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

53. Unless enjoined by the Court, Hikma will induce infringement of the '938 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell MITIGARE™ in the United States.

54. On information and belief, Hikma will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using MITIGARE™, with knowledge of the '938 Patent and knowledge that its acts are encouraging infringement.

55. Takeda will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court.

56. Takeda does not have an adequate remedy at law.

57. Takeda requests a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of MITIGARE™ before the '938 Patent expires will induce infringement of one or more claims of the '938 Patent.

COUNT IV

(Declaratory Infringement of the '655 Patent Under 35 U.S.C. § 271(b))

58. Paragraphs 1 to 57 are incorporated herein as set forth above.

59. There is an actual and substantial controversy between Takeda and Hikma regarding the imminent infringement of the '655 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

60. Unless enjoined by the Court, Hikma will induce infringement of the '655 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell MITIGARE™ in the United States.

61. On information and belief, Hikma will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using MITIGARE™, with knowledge of the '655 Patent and knowledge that its acts are encouraging infringement.

62. Takeda will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court.

63. Takeda does not have an adequate remedy at law.

64. Takeda requests a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of MITIGARE™ before the '655 Patent expires will induce infringement of one or more claims of the '655 Patent.

COUNT V

(Declaratory Infringement of the '722 Patent Under 35 U.S.C. § 271(b))

65. Paragraphs 1 to 64 are incorporated herein as set forth above.

66. There is an actual and substantial controversy between Takeda and Hikma regarding the imminent infringement of the '722 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

67. Unless enjoined by the Court, Hikma will induce infringement of the '722 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell MITIGARE™ in the United States.

68. On information and belief, Hikma will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using MITIGARE™, with knowledge of the '722 Patent and knowledge that its acts are encouraging infringement.

69. Takeda will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court.

70. Takeda does not have an adequate remedy at law.

71. Takeda requests a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of MITIGARE™ before the '722 Patent expires will induce infringement of one or more claims of the '722 Patent.

PRAYER FOR RELIEF

WHEREFORE, Takeda requests entry of judgment in its favor and against West-Ward, Hikma Americas, and Hikma Pharmaceuticals as follows:

A. Declaring and entering judgment that West-Ward, Hikma Americas, and Hikma Pharmaceuticals will infringe one of more claims of the COLCRYS® Patents under 35 U.S.C. § 271(b) by its manufacture, use, offering to sell, and sale in, and importation into the United States of West-Ward's, Hikma Americas, and Hikma Pharmaceuticals' MITIGARE™ product prior to the expiration of those patents;

B. A judgment preliminarily and permanently enjoining West-Ward, Hikma Americas, and Hikma Pharmaceuticals, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on their behalf, from any commercial manufacture, use, offer to

sell or sale within the United States, or importation into the United States, of any drug product that infringes the COLCRYS® Patents;

C. That if West-Ward, Hikma Americas, and Hikma Pharmaceuticals engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of its MITIGARE™ (colchicine) 0.6 mg capsule product before the latest expiration date of the COLCRYS® Patents, a judgment be awarded to Takeda for damages resulting from such infringement, together with interest, in an amount to be determined at trial;

D. Declaring this an exceptional case under 35 U.S.C. § 285, and that Takeda be awarded reasonable attorneys' fees and costs; and

E. Such other and further relief as the Court may deem just and proper.

Date: October 3, 2014

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